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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/792,355

03/03/2004

Bruno Pfeiffer

SERVIER 396 PCT

5116

25666

7590

10/16/2006

EXAMINER

SHIAO, REI TSANG

THE FIRM OF HUESCHEN AND SAGE  
SEVENTH FLOOR, KALAMAZOO BUILDING  
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KALAMAZOO, MI 49007

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/792,355

Applicant(s)

PFEIFFER ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 23, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                             |                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/14/06</u> | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. **This Office action supersedes the previous Office action mailed on September 28, 2006.**

2. This application claims benefit of the foreign application:

FRANCE 00/08793 with a filing date 07/06/2000; and FRANCE 00/08973 with a filing date 07/06/2000. However, the foreign priority document FRANCE 00/08973 has not been filed to the Office. Applicants are requested to file the foreign priority document to the Office.

3. Applicant's arguments/remarks and a declaration under 37 CFR 1.132 filed on August 14, 2006, are acknowledged. Claims 14-26 are pending in the application.

### ***Information Disclosure Statement***

4. Applicant's Information Disclosure Statement, filed on August 14, 2006, has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

### ***Prior Art Rejections***

5. In regards to the claimed compound, the prior art reference of Vincent et al. US 4,914,214 or Guez et al. US 6,653,336 does not provide applicants' instant X-ray power diffraction data. However, Vincent et al. do name the instant crystalline compound (i.e., crystallized), and Guez et al. do name the instant compound, which puts this product in the public domain, see line 5-31 in column 10 of Vincent et al, or see Examples 1-2 in column 4 of Guez et al. As these forms differ from the claims in that the reference are

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silent on the X-ray diffraction data, applicants must show that their crystalline form really is different from any crystalline forms prepared in the prior art. MPEP 2112 states: "Something which is old does not become patentable upon the discovery of a new property. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, see *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In this case, the "unknown property" is the particular crystalline form. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state: "A rejection under 35 USC 102/103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristic. Where applicant claims a composition in terms of a function, property or characteristic and the compositions of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection." Here, the prior art is silent on is the X-ray diffraction pattern data. Nevertheless, this "characteristic" is inherent, therefore, explicit disclosure is not required.

Here the reference explicitly teaches the same compound. The only difference is a characteristic about which the reference happens to be silent, also see *Ex parte Anderson*, 21 USPQ 2nd 1241 and 1251. There, the decision states: "There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture." (page 1253).

***Responses to Arguments***

6. Applicant's arguments regarding the rejection of claims 14, 23 and 25-26 under 35 U.S.C. 102(b), 102(e), or 103 (a) filed on August 14, 2006, have been fully considered and they are persuasive, in part. Applicants argue that the instant  $\alpha$  crystalline compound of formula (I), i.e., perindopril of tert-butylamine salt, is distinct from Vincent et al., and distinctness between the instant  $\alpha$  crystalline and prior art has been provided by Dr. Gerard Coquerel's declaration, and it is persuasive. The instant X-ray diffraction pattern data and stability data of  $\alpha$  crystalline is distinct from Vincent et al. The rejection of claims 14, 23 and 25-26 over Vincent et al. '214 under 35 U.S.C. 102(b) or 103 (a) has been withdrawn herein. However, Guez et al. disclose the instant compound and its pharmaceutical compositions and are silent on the X-ray diffraction pattern data. Therefore, absent a showing of unobvious and superior properties in terms of mechanic benefits, the instant claimed compound/compositions of known compound/compositions would have been suggested to one skilled in the art. The rejection of claims of 25-26 over Guez et al. '336 (i.e., or WO 99/25374) under 35 U.S.C. 103 (a), is maintained. It is noted that Guez et al. '374 or '336 disclose the instant compound perindopril, tert-butylamine salt and its pharmaceutical composition, see lines 11-50 in column 3 of Guez et al. '336. Therefore, claims 14 and 23 are also rejected over Guez et al. '374 or '336 under 35 U.S.C. 102 (b) or 102 (e) respectively.

7. Applicant's arguments regarding the provisional rejection of claims 14, 23 and

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25-26 under the obvious-type double patenting filed on August 14, 2006, have been fully considered and they are persuasive, in part. Since the instant X-ray diffraction pattern data of the  $\alpha$  crystalline form is distinct from Pfeiffer et al. '489, the rejection of claim 14 under the obvious-type double patenting has been withdrawn herein.

However, it is well recognized in the art that process of preparing pharmaceutical composition will produce the thermodynamically stable form of crystals, thus, Pfeiffer et al.  $\beta$  crystal form and the instant  $\alpha$  crystalline form, after mixing, grinding, compressing would both be transformed into the same thermodynamically stable form(s) of the instant form (i.e.,  $\alpha$  crystalline form), see Brittain's publication, pages 348-361.

Therefore, the rejection of claims 23 and 25-26 under the obvious-type double patenting, is maintained. Applicants are requested to file a terminal disclaimer to overcome the rejection.

**8. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*R.S.*

Robert Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

October 06, 2006

*Joseph K. McKane*

Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626